REMARKS

Claims 1-14 and 17 are pending.

35 U.S.C. 112

Claims 1-14 and 17 were rejected for lack of clarity regarding the language, "or physiologically functional derivative thereof." Applicants wish to call attention to the specification at page 4, lines 30-32, where the language is expressly clarified and defined. Accordingly, it is submitted that this overcomes the rejection under 35 U.S.C. 112, second paragraph.

Double Patenting

Claims 1, 2, 10, 11, 13 and 14 were provisionally rejected on the ground obviousness-type double patenting over claims 1-14 of copending application 10/510,147. Applicants respectively request reconsideration because the claims of the two cases actually have certain critical distinctions rendering them nonobvious in view of each other.

Specifically, while formoterol is common to both claim sets, the present claims all also require mometasone, whereas the claims of 10/510,147 all require ciclesonide. Moreover, the present claims require both the formoterol and mometasone to be in the form of particulate suspensions, whereas the claims of 10/510,147 require the formoterol to be in the form of a particulate suspension but the ciclesonide to be in the form of a solution.

It is submitted that claims to formoterol particulate suspension + mometasone particulate suspensions would not be obvious over claims to formoterol particulate suspension + ciclesonide solution.

35 U.S.C. 103

Claims 1-14 and 17 were rejected under 35 USC § 103(a) as being unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

Section 8 of the Office Action asserts that the particle size of the bulking agent in Trofast et al. reads on the particle size of the instant invention. Consistent with that view none of

obviousness analysis in the Office Action mentions the claim limitation requiring the bulking agent to have a mass median diameter of less than 1 micron.

Applicants respectfully request reconsideration of whether Trofast et al. discloses a MDI formulation with a bulking agent, particularly one having a mass median diameter under 1 micron.

Applicants wish to emphasize that in the context of an MDI formulation use of a bulking agent in having submicron particle size was (a) not standard or conventional at the time, and (b) is an important feature of the claimed invention as evident from its repeated discussion on page 3 of the application under Summary of the Invention.

Trofast et al. is devoid of any meaningful disclosure of any use of bulking agent in the context of an MDI formulation and certainly not one using nano-sized particles. Trofast et al. references a diluent or carrier at page 5, line 28, through page 6, line 11, in such a way that it is clearly contemplating use in a dry powder inhaler (DPI). The powdered drug formulations used in DPIs normally have such diluents or carriers, and the language at page 5, line 30, ". . . added to the *powdered medicament* . . ." (italic added) is clearly alluding to DPI application. Trofast et al. states at page 6, line 13, "When the ingredients of the system are adapted to be administered from a pressurized inhaler . . . ," but this is far to vague and insufficient to constitute any meaningful disclosure of an MDI formulation using a bulking agent.

It is also worth observing that, even though in the DPI context, the smallest size range mentioned in Trofast et al. at page 6, line 11, merely states ". . . preferably less than 10 μm." While this is an upper end and expressly references the active ingredients (not diluent or carrier), it is nonetheless 10 times the maximum size range called for the bulking agent in the present claims.

It is submitted that a prima facie case of obviousness has not been established where, as here, Trofast et al. fails to clearly disclose any MDI formulation with a bulking agent, and completely fails to disclose the important sub-micron size of the bulking agent required by the present claims.

Accordingly, in view of the above, reconsideration and favorable action are requested.

Respectfully submitted,

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